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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/438,872	11/12/1999	KENT C. COCHRUM	44041.010400	9965
26191	7590	04/18/2006	EXAMINER	
FISH & RICHARDSON P.C.			MARX, IRENE	
PO BOX 1022			ART UNIT	
MINNEAPOLIS, MN 55440-1022			PAPER NUMBER	

1651

DATE MAILED: 04/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/438,872	<b>Applicant(s)</b> COCHRUM ET AL.	
	<b>Examiner</b> Irene Marx	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 47-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 47-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                                   |                                                                                         |
|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                              | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

Art Unit: 1651

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/10/06 has been entered.

The rejection under double patenting over Application No. 10/334864 is withdrawn in view of applicant's proper terminal disclaimer filed.

Applicants' arguments regarding Application No. 11/145678 are moot in view of the preliminary amendment filed in that case.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 52 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 52 is incomplete in depending on itself.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1651

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 47 is rejected under 35 U.S.C. 102(b) as being anticipated by Dardik (U.S. Patent No. 4,848,329).

The claims are directed to a dressing composition consisting essentially of a gauze matrix and cross-linked dextran beads in powder form on a particular wound contacting side of the gauze matrix.

Dardik discloses a dressing comprising a gauze matrix and cross-linked dextran beads in powder form on a particular wound contacting side of the gauze matrix. See, e.g., Example 1. Inasmuch as the gauze matrix openings are of a size of 0.1 mm or less and the cross-linked dextran has a diameter of 0.1 mm and given the pliability of gauze and its thickness of less than 0.1 mm, the dextran powder is on a wound contacting surface at least to some extent.

It is noted that neither the quantity of beads in powder form on a particular side of the gauze nor their adherence to the gauze is specified with any particularity.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz , 537 F.2d 549, 551 - 52, 190 USPQ 461, 463 (CCPA 1976)(emphasis in original)(Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well - known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). See also Atlas Powder Co. v. E.I. duPont de Nemours & Co. , 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama - Rao, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); Water Technologies Corp. v. Calco, Ltd ., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting

Art Unit: 1651

essentially of," **applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention.** In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063 - 64 (Bd. Pat. App. & Inter. 1989)("Although 'consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps . . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification . . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by 'consisting essentially of' language.").

In the absence of a clear definition of "consisting essentially of" in the specification, the terminology is interpreted as "comprising".

Claims 47-53 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson & Johnson (U.K. Patent No. 629,419) or Patel (U.S. Patent No. 5,470,576) taken with G.B. 1454055 and Dardik (U.S. Patent No. 4,848,329 )

The claims are directed to a dressing consisting essentially of a gauze matrix and cross-linked dextran beads in powder form on a particular wound contacting side of the gauze matrix.

Each of Johnson & Johnson and Patel discloses a wound dressing comprising a gauze consisting of a gauze matrix and a polysaccharide such as alginate on a particular wound contacting side of the gauze matrix (See, e.g., Johnson & Johnson, page 2, col. 1, lines 163 and col. 2, lines 92-112 or Patel, Example 3).

The references differ from the claimed invention in that the gauze does not have cross-linked dextran beads on a particular wound-contacting surface of the gauze. However, G.B. 1454055 discloses a removable dry wound dressing comprising cross-linked dextran beads on a particular wound contacting surface. See, e.g., Example 5. Even though the material used is not disclosed as being gauze specifically, the reference envisions using a cotton fabric (page 8, line 38) which clearly encompasses gauze. In addition, given that the removable wound dressing comprises beads in powder form that are uniformly distributed between the fibers, one of ordinary skill in the art would reasonably have expected that the surface would have dextran

Art Unit: 1651

beads on a particular wound-contacting surface of the matrix which would be in "powder form" at least to some extent.

In addition, Dardik discloses a dressing comprising a gauze matrix and cross-linked dextran beads in powder form on a particular wound contacting side of the gauze matrix. See, e.g., Example 1. Inasmuch as the gauze matrix openings are of a size of 0.1 mm or less and the cross-linked dextran has a diameter of 0.1 mm and given the pliability of gauze and its thickness of less than 0.1 mm, the dextran powder is on a wound contacting surface at least to some extent. Even though the dextran material used in the reference has a lower exclusion limit than that of the claimed invention, one of ordinary skill in the art would have had compelling motivation at the time the claimed invention was made to use a variety of dextran bead powders with a reasonable expectation of success in obtaining compositions having similar useful properties.

It is noted that neither the quantity of beads in powder form on a particular side of the gauze nor their adherence to the gauze is specified with any particularity.

Moreover, the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In *re Herz*, 537 F.2d 549, 551 - 52, 190 USPQ 461, 463 (CCPA 1976)(emphasis in original)(Prior art hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any well-known additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). See also *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In *re Janakirama - Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. v. Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," **applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention.** In *re*

Art Unit: 1651

De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063 - 64 (Bd. Pat. App. & Inter. 1989) ("Although 'consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps . . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification . . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by 'consisting essentially of' language.").

In the absence of a clear definition of "consisting essentially of" in the specification, the terminology is interpreted as "comprising".

The molecular weight exclusion limit of at least 270,000 discussed in the British patent '055 appears to be substantially the same as claimed. (See, e.g., page 2, lines 3-9). However, even if it is not, the selection of a cross-linked dextran polymer coating for optimization purposes identified as result-effective variables cited in the references would have been *prima facie* obvious to a person having ordinary skill in the art, since such selection is at the essence of biotechnical engineering and dextran beads in powder form are easily available from commercial sources and one of ordinary skill in the art would have recognized their suitability for the composition of '055 for example.

Accordingly, one of ordinary skill in the art would have had a reasonable expectation of success in substituting gauze having cross-linked dextran in powder form having a variety of molecular weight exclusion limits on a wound contacting side for a gauze having an alginate coating because both of the polysaccharide polymers alginate and dextran have suitable properties for use in gauze bandages, such as being hemostatic and preventing adhesion.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the gauze coated with alginate as taught by Johnson & Johnson or Patel by substituting therefor a gauze matrix having cross-linked dextran in powder form molecular weight exclusion limits on a wound contacting side as taught by G.B. 1454055 and Dardik for the expected benefit of obtaining a dry, removable wound dressing which is more

Art Unit: 1651

pliable and more easily removable and which has the hemostatic properties provided by dressing consisting essentially of gauze and a cross-linked dextran polymer powder.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

### ***Response to Arguments***

Applicant's arguments as they pertain to the above rejection have been fully considered but they are not deemed to be persuasive.

Applicant argues that the '055 reference is not anticipatory. Yet this argument is not material to an obviousness rejection. Applicant argues that the '055 reference does not disclose cross-linked dextran beads on a particular side of a gauze matrix. The reasoning behind this contention is not clearly delineated. In the instant claims, the dextran powder is not limited to being on one side of a gauze matrix, but rather <sup>to</sup> "on a particular wound-contacting side of said gauze matrix", which recitation does not exclude the presence of dextran powder elsewhere in or on the gauze. In other words, that the dextran powder is on a particular side of the gauze does not preclude the powder from being distributed throughout the gauze matrix. In fact, the dextran bead powder is not required to adhere to a particular wound contacting surface of the gauze but could arguably detach from the gauze upon contacting a wound or even remain partially or *in toto* in packaging material.

Similarly, applicants argue that none of the references relied upon by the Examiner teach or suggest the claimed invention. However, "[n]on-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references." In re Merck & Co. Inc, 800 F.2d 1091, 1097, 231 USPQ 375, 380 (Fed. Cir. 1986). The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." In re Gorman, 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991).

The prior art recognizes the benefits of having gauze with a polysaccharide such as alginate or crosslinked dextran beads in powder form on a wound-contacting surface. The '055 and Dardik patents demonstrate that a composition consisting essentially of a cotton fabric or gauze and crosslinked dextran powder on a wound-contacting surface is old and well known in the art. The dextran material used in the reference is substantially the same as claim designated.



Art Unit: 1651

As noted *supra* the terminology "consisting essentially of" in the claim is interpreted as open claim language, i.e., it is interpreted as "comprising".

Note still further that, contrary to applicant's argument, it is well established that motivation for combining references need not come from the references themselves, as long as applicant's disclosure is not improperly used in a hindsight reconstruction of the claimed invention. See *Ex parte Levengood*, 28 USPQ2d 1300 (1993), at 1301. ("Motivation for combining the references need not be explicitly found in the references themselves. Indeed, the examiner may provide an explanation based on logic and sound scientific reasoning that will support a holding of obviousness.") (Citations omitted.)

Even though the '055 patent does not explicitly disclose a composition having dextran powder on a gauze surface, it does teach the use of coated cotton fabric, which is generally woven, in addition to cellulose fibers or paper pulp in conjunction with dextran beads. See, e.g., Example 5, in particular, page 8, line 38. In addition, one of ordinary skill in the art would have reasonably expected that the Dardik composition would have dextran beads in powder form on a surface at least to some extent. Therefore the substitution of these materials with a cotton fabric such as gauze is clearly suggested by the teachings of the '055 reference, Dardik and the Johnson & Johnson or Patel references. It is emphasized that the claims are directed to a composition rather than to a method of accelerating the coagulation of blood.

The arguments directed to Smith are moot, since this reference is no longer relied upon in the rejection.

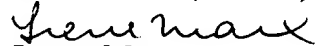
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Irene Marx  
Primary Examiner  
Art Unit 1651